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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,860	07/11/2006	Young-Ho Kim	123038-06084375	7729

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LOWE HAUPTMAN HAM & BERNER, LLP
1700 DIAGONAL ROAD
SUITE 300
ALEXANDRIA, VA 22314

EXAMINER

GABEL, GAILENE

ART UNIT	PAPER NUMBER
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1641

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/585,860	Applicant(s) KIM ET AL.	
	Examiner GAILENE R. GABEL	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 May 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/11/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. Claims 1-15 are pending and are under examination.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, first step in lines 2-4, is vague and indefinite in reciting, “accommodated in an upwardly convex shape” because it is unclear what Applicant intends in using the term “accommodated”, especially in an “upwardly convex shape”. Does Applicant perhaps intend, “contained” instead of “accommodated.” See also claim 12, step a).

Claim 1, second step in lines 5-7, is also vague and indefinite in reciting, “accommodated in the cell mixture holding portion” because it is unclear what Applicant intends in using the term “accommodated.” Does Applicant perhaps intend, “contained”

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instead of “accommodated.” See also claim 1, line 13 which recites, “accommodated” and claim 4, line 2 which recites, “accommodating.”

Claim 1, lines 16-21 is indefinite in lacking clear antecedent basis in reciting, “the specific cells moved toward the upper plate by means of a magnetic field applied... through the magnetic field applying means” and “cells other than the specific cells moved toward the lower plate by means of gravity... are divided and then positioned ...”. Does Applicant perhaps intend, “the specific cells tagged with magnetic carriers move toward the upper plate by means of a magnetic field applied... through the magnetic field applying means” and “the cells that are not tagged with magnetic carriers move toward the lower plate by means of gravity... and are caused to be divided and then positioned ...”.

In claim 1, line 18, lacks clear antecedent basis in reciting, “the created cell mixture layer.” Perhaps, Applicant intends, “the formed cell mixture layer” which is consistent with line 14 which recites, “and then formed into a cell mixture layer.”

In claim 3, line 6, is indefinite in reciting, “the lower plate and the gap adjusting means are installed within the lower plate.” It appears that it should recite, “the lower plate and the gap adjusting means are installed within the lower housing.”

Claim 7, lines 6-7 is ambiguous in reciting, “the lower plate support is brought into contact with a plurality of steps with different levels decreasing from one side to another side” because it is unclear what is encompassed in the recitation of “steps with different levels” as recited in the claim.

Claims 12-15 provide for the a cell separation method, but, since the claims do not clearly set forth any decipherable positive and active method steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites what appear to be mental steps without any active, positive steps delimiting how this use is actually practiced.

In this case, the method steps, “creating a cell mixture”, “moving the specific cells”, “allowing the specific cells”, and “homogenizing the specific cell mixture” appear to recite mental steps because they fail to clearly define method steps utilizing the claimed apparatus.

Claims 12-15 are rejected under 35 U.S.C. 101 because the claimed recitation of mental steps, without setting forth any decipherable positive and active method steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).”

In the case of the instant invention encompassing Applicant's apparatus, it appears that the recited mental steps are perhaps clearly performed by the following active method steps utilizing Applicant's claimed apparatus at least for claim 12:

- “decreasing a gap between the upper and lower plates using the gap adjusting means to create a cell mixture layer comprising a cell mixture containing specific cells tagged with magnetic beads, such that the cell mixture contained in an upwardly convex shape in the cell mixture

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holding portion of the lower plate is caused to be adsorbed in a bottom surface of the upper plate position opposite to the cell mixture holding portion of the lower plate;"

- "applying a magnetic field to the cell mixture layer in step a) by the magnetic field applying means to move the specific cells tagged with magnetic beads toward the upper plate while simultaneously allowing cells not tagged with magnetic beads to move toward the lower plate by means of gravity;" and
- "increasing the gap between the upper and lower plates using the gap adjusting means to allow specific cells tagged with magnetic beads moved toward the upper plate in step b) to be positioned in the bottom surface of the upper plate and the cells not tagged with magnetic beads moved toward the lower plate to be positioned in the cell mixture holding portion of the lower plate so as to allow the cell mixture layer to be divided and separated."

Claim 12, step b) is indefinite in lacking clear antecedent basis in reciting, "the specific cells toward the upper plate" and "the other cells... toward the lower plate."

Does Applicant perhaps intend, "the specific cells tagged with magnetic carriers toward the upper plate" and "the cells that are not tagged with magnetic carriers toward the lower plate." See also claim 14, step f1) and claim 15, step f2).

Claim 12, step c) is indefinite in lacking clear antecedent basis in reciting, "the specific cells moved toward the upper plate" and "the other cells moved toward the

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lower plate” to be divided and then positioned ...”. It is specifically what is encompassed in reciting, “the other cells.” See also claim 14, step g1) and claim 15, step g2).

Claim 14, step d1) is confusing in reciting, “a specific cell mixture layer” because it is unclear how the instant “a specific cell mixture layer” relates to “the cell mixture layer” in claim 12, step c) from which claim 14 depends. Should claim 14, step d1) recite, “another specific cell mixture layer.”

Claim 14, step d1) is ambiguous in failing to clearly define what is encompassed within the recitation of “the other cells” as recited in the claim. Perhaps, Applicant should recite, “the other cells that are not tagged with magnetic carriers.”

Claim 14, step e1) is objected to in reciting, “repeatedly several time.” It should recite, “repeatedly several times.”

Claim 15, step d2) is ambiguous in failing to clearly define what is encompassed within the recitation of “the specific cells” as recited in the claim. Perhaps, Applicant should recite, “the specific cells tagged with magnetic carriers.”

Free of the Prior Art

4. Claims 1-15 are free of the prior art. Claims 1-15 would be allowable if rewritten or amended to overcome the rejections under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

The prior art of record fails to teach or fairly suggest a cell separation apparatus and method whereupon a gap adjusting means that is coupled to an upper plate and a

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lower plate of the apparatus that adjusts gap between the upper plate and the lower plate is adjusted to decrease the gap so as to incorporate a cell mixture containing cells tagged with magnetic beads contained in the cell mixture holding portion of the lower plate into the upper plate so that the bottom surface of the upper plate adsorbs the cell mixture, thus forming a cell mixture layer between the upper plate and the lower plate, whereupon magnetic field is applied by a magnetic field applying means located on the upper plate to move specific cells tagged with magnetic beads towards the upper plate and simultaneously allow cells not tagged with magnetic beads to move toward the lower plate by gravity. Thereafter, the gap adjusting means is adjusted to increase the gap between the upper plate and the lower plate so as to separate the specific cells tagged with magnetic beads that have moved towards the upper plate and the cells not tagged with magnetic beads that have moved toward the lower plate by gravity, and then divide and positioned in the bottom surface of the upper plate and the cell mixture holding portion of the lower plate, respectively.

5. No claims are allowed.

Remarks

6. The following lists the closest prior art made of record as being pertinent to Applicant's disclosure:

Vellinger et al. (US Patent 6,312,910) disclose a multistage electromagnetic cell separation apparatus designed to separate magnetically tagged cells suspended in

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fluid. The apparatus comprises a lower plate and an upper plate set to a fill position. The lower plate is provided with a cell mixture holding portion (lower cuvette) whereupon a cell mixture comprising specific cells tagged with magnetic beads are contained (Abstract). The apparatus further comprises a magnetic field applying means (holding electromagnet or permanent magnet) which is positioned on the top surface of the upper plate and is positioned above the lower plate so as to face each other. The upper plate has a bottom surface made of polycarbonate that has a capability of absorbing the cell mixture contained in the cell mixture holding portion. When magnetic field is applied by the magnetic field applying means, the specific cells that are magnetically tagged move toward the upper plate. (Figure 3; Figure 13; col. 9, line 64 to col. 10, line 11; col. 10, lines 43-54). The unwanted cells that are not tagged by magnetic beads are simply left behind to move and settle to the lower plate by gravity (col. 4, lines 11-18; col. 10, lines 12-21). The upper plate and the magnetic field applying means are installed within an upper housing (col. 10, lines 48-54).

Mahant et al. (US Patent 6,821,790) disclose a cell separation apparatus that has a plurality of confining walls within which a cell sample comprising cells that are tagged with magnetic beads are retained, and at least one of the confining walls is flexible (col. 3, lines 33-47). Separation of cell populations takes place using two forces using magnetic field applying means to apply a magnetic field (force) and an electromechanical hydraulic applying means to apply electromechanical hydraulic force (col. 3, lines 55-65). The flexible confining wall can be substantially deformed employing moderate pressure without breaking or damaging the confining wall. All of

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the walls may be flexible; thus allowing an increase or decrease of gap between the confining walls. In this case, a magnetic force will retain the cell layer mixture containing the cells that are tagged by magnetic beads (cell-depleted portion) within the confining walls while mechanical force by one or more actuators compressing the vessel which causes a decrease in gap between the confining walls, assist in separation of the cells not tagged with magnetic beads (col. 7, lines 34-40).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GAIENE R. GABEL whose telephone number is (571)272-0820. The examiner can normally be reached on Monday, Tuesday, Thursday, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark L. Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GAILENE R. GABEL/
Primary Examiner, Art Unit 1641

March 24, 2009